2/9/99

I-FLOW
CORPORATION

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K984063

SUMMARY OF SAFETY AND EFFECTIVENESS

November 11, 1998

Trade Name: Paragon Infusion Kit

Common Name: Infusion Pump Kit

Classification Name: Pump, Infusion

All questions and/or comments concerning this document should be made to:

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1.0 GENERAL INFORMATION

1.1 Purpose of Submission

1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to market a new intended use for the Paragon Infusion System (K923875), originally identified as the SideKick 50 Plus and SideKick 100 Plus. The Paragon will be marketed as a kit, the Paragon Infusion Kit, including labeling changes and additional components.

1.1.2 Trade Name: Paragon Infusion Kit

1.1.3 Common Name: Infusion Pump Kit

1.1.4 Classification Name: Pump, Infusion

1.1.5 Classification Panel: General Hospital and Personal Use Device

1.2 Statement of Equivalence

1.2.1 The Paragon Infusion Kit includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

1.2.2 The Paragon pump and administration set are the same as used in K923875.

1.2.3 The Paragon Kit is substantially equivalent to the I-Flow Paragon Infusion System (K923875), the I-Flow PainBuster Infusion Kit (K980558, K982946), the Sgarlato Pain Control Infusion Pump (PCIP) (K896422) and the I-Flow Homepump C-Series (K944692).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the Paragon Infusion Kit

2.1.1 The Paragon Infusion Kit is identical to the I-Flow PainBuster Infusion Kit with the exception of the Paragon pump and administration set replacing the PainBuster pump.

2.1.2 The kit is comprised of a Paragon pump and administration set (K923875) and various kit components such as catheter, needle, syringe, Y adapter, dressing, tape, gauze and carry case.

2.1.2.1 The PainBuster kit contains all the above components except for an elastomeric pump with integrated administration set instead of the Paragon pump and administration set.

2.1.3 The Paragon administration set is intended to attach to the kit catheter at the distal end of the set to provide continuous infusion of a local anesthetic directly into the intraoperative site for general surgery for postoperative pain management.

2.1.4 The Paragon administration set is a disposable device intended for single patient use. The Paragon pump is reusable.

2.1.5 The Paragon is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

2.2 Description of Paragon Pump

2.2.1 The Paragon pump consists of two cylindrical shells. The top half of the pump has internal threads which mate to the external threads of the bottom half of the pump.

2.2.2 The top incorporates a pressure plate which applies a load to the pliable drug bag. The load is applied to the drug bag by way of two opposing springs which act upon a scissors mechanism. The spring/scissors mechanism creates a near constant pressure in the drug bag.

2.2.3 The bottom half of the pump is slotted to allow for positioning of the administration set.

2.2.4 When the top and bottom halves of the pump are fully threaded together, the pressure plate contacts the drug bag and acts as the pressurizing element.

2.2.5 This premarket notification proposes no changes to the Paragon pump.

2.3 Description of Paragon Administration Set

2.3.1 The Paragon administration set consists of a PVC drug bag attached to the administration line.

2.3.2 Each administration set consists of fixed diameter flow control tubing or glass orifice.

2.3.3 The flow control tubing or glass orifice is cut to a specific length L. When the PVC drug bag is pressured by the Paragon pump, the delivery times are defined by the inside diameter of the flow control orifice.

2.3.3.1 The delivery time characteristic is derived from the flow rate of the device which is in turn approximated by Poiseulle's equation:

$$Q = \frac{\Delta \rho \pi D^4}{128 \mu L}$$

2.3.3.2 Where Q is the flow rate, ρ is the pressure drop across the orifice, D is the inside diameter of the flow controlling orifice, μ is the dynamic viscosity of the fluid and L is the length of the orifice. The equation provides an approximation of the actual delivery time.

2.4 Product Configuration

2.4.1 The Paragon pump:

2.4.1.1 PG100000P: 100 ml volume

2.4.2 The Paragon administration sets:

2.4.2.1 PG100005: 100 ml volume, 0.5 ml/hr flow rate

2.4.2.2 PG100010: 100 ml volume, 1.0 ml/hr flow rate

2.4.2.3 PG100020: 100 ml volume, 2.0 ml/hr flow rate

2.4.2.4 PG100040: 100 ml volume, 4.0 ml/hr flow rate

2.4.2.5 PG100100: 100 ml volume, 10.0 ml/hr flow rate

2.4.2.6 PG100020Y: 100 ml volume, 2.0 ml/hr flow rate, dual orifice, dual catheter with Y adapter

2.4.2.6.1 The dual orifice set consists of a standard Paragon set with dual orifice downstream from the Y adapter. Each orifice allows 2 ml/hr flow rate.

2.4.3 Each model consists of a kit with the following components:

2.4.3.1 Paragon pump (optional).

2.4.3.1.1 The reusable Paragon pump may be packaged and sold separately from the disposable kit components.

2.4.3.2 Paragon administration set.

2.4.3.3 Catheter:

2.4.3.3.1 18 to 22 G catheter, 11 to 40 in. length, polyamide, nylon, FEP (fluorinated ethylene propylene) polymer, silicone, polyurethane or Teflon.

2.4.3.3.2 A catheter connector is included to connect the catheter to the distal luer of the administration set.

2.4.3.3.3 The B. Braun Perifix® Epidural Catheter Set is an example of the type of catheter that may be used with the Paragon Infusion Kit.

2.4.3.3.3.1 Product code: EC20-0.

2.4.3.3.3.2 510(k) number: K813186.

2.4.3.4 Needle:

2.4.3.4.1 14 to 18 G, 1 ½ to 3 ¼ in. length, stainless steel.

2.4.3.4.2 The needle may be a catheter over needle as in the Angiocath™ example below.

2.4.3.4.3 The Angiocath catheter introducer needle is an example of the type of catheter introducer needle that may be used with the Paragon Infusion Kit.

2.4.3.4.3.1 Product code: 382258.

2.4.3.5 Syringe (optional):

2.4.3.5.1 60 cc plastic, luer lock syringe.

2.4.3.5.2 The syringe is used to fill the Paragon drug bag with medication.

2.4.3.5.3 The B-D 60 cc syringe is an example of the type of syringe that may be included in the Paragon Kit.

2.4.3.5.3.1 Product Code: 309663.

2.4.3.6 Dressing (optional):

2.4.3.6.1 The dressing is used to hold the catheter and/or flow restrictor in place.

2.4.3.6.2 The OpSite™ is an example of the type of dressing that may be used in the Paragon Kit.

2.4.3.6.2.1 Product Code: 4973.

2.4.3.7 Carry Case (optional):

2.4.3.7.1 The carry case is used to hold the Paragon pump while delivering medication.

2.4.3.7.1.1 I-Flow part numbers 1400749, 1400752 or 1400758.

2.4.3.8 Antiseptic Skin Swabs (optional):

2.4.3.8.1 The antiseptic skin swabs are used to prep the skin area of the patient prior to inserting the catheter.

2.4.3.8.2 The Alcohol Prep Pads or Iodophor PVP Scrub Swabsticks manufactured by Clinipad Corporation are examples of the type of antiseptic skin swabs that may be used in the Paragon Kit.

2.4.3.8.2.1 Model number: CL0110.

2.4.3.8.2.2 Model number: CL1244.

2.4.3.9 Tape (optional):

2.4.3.9.1 The tape may be used to the secure catheter, flow control tubing or gauze.

2.4.3.9.2 The Transpore™ Surgical Tape manufactured by 3M is an example of the type of tape that may be used in the Paragon Kit.

2.4.3.9.2.1 Model number: 3M1527-1.

2.4.3.10 Gauze (optional):

2.4.3.10.1 The gauze may be used to secure the catheter or flow control tubing.

2.4.3.10.2 The Kling® Conforming Gauze manufactured by Johnson and Johnson is an example of the type of gauze which may be used in the Paragon Kit.

2.4.3.10.2.1 Model number: JJ6923.

2.4.3.11 Y Adapter (optional)

2.4.3.11.1 The Y adapter is used for an additional catheter for a large wound or multiple wound sites.

2.4.3.11.2 The Flexible Y Fitting by Qosina is an example of the type of Y Adapter that may be used in the Paragon Kit.

2.4.3.11.2.1 Model number: 81120.

2.5 Components and Materials

The pump and administration sets used in the Paragon Infusion Kit are currently available models of the Paragon Infusion System (K923875). No changes will be made to the Paragon pump or administration sets.

All kit components other than the pump and administration set are identical to those used in the PainBuster infusion system submitted under K980558, K982946.

The Paragon administration set is a disposable device intended for single patient use. The Paragon pump is reusable.

2.6 Power Requirements

2.6.1 The Paragon pump is a mechanical pump that utilizes spring energy for power. No additional external power source is required.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 Standard Operating Conditions:

Priming/Residual Volume:	< 5 ml
Operating Temperature:	31°C skin temperature (90°F)
Test Solution:	0.9% NaCl
Operating Pressure:	6.0 psi pressure source
Head Height:	0"
Accuracy:	±10% at 95% confidence interval

3.2 **Flow Rate Performance Data**: Testing occurred at standard operating conditions. All models produced an average flow rate within the ±10% accuracy claim.

	100 ml x 0.5 ml/hr	100 ml x 1 ml/hr	100 ml x 2 ml/hr	100 ml x 4 ml/hr	100 ml x 10 ml/hr
Average Flow Rate (ml/hr)	0.53	0.99	1.99	4.14	10.30
Std. Dev.	0.01	0.03	0.07	0.10	0.38
N	5	5	5	5	10

100 ml x 0.5 ml/hr: A five (5) piece sample produced an average flow rate of 0.53 ml/hr. The resulting average is well within its ±10% accuracy claim. The fastest infusion had an average flow rate of 0.54 ml/hr and the slowest infusion had an average flow rate of 0.51 ml/hr.

100 ml x 1.0 ml/hr: A five (5) piece sample produced an average flow rate of 0.99 ml/hr. The resulting average is within its ±10% accuracy claim. The fastest infusion had an average flow rate of 1.04 ml/hr and the slowest infusion had an average flow rate of 0.96 ml/hr.

100 ml x 2.0 ml/hr: A five (5) piece sample produced an average flow rate of 1.99 ml/hr. The resulting average is within its ±10% accuracy claim. The fastest infusion had an average flow rate of 2.05 ml/hr and the slowest infusion had an average flow rate of 1.90 ml/hr.

100 ml x 4.0 ml/hr: A five (5) piece sample produced an average flow rate of 4.14 ml/hr. The resulting average is within its ±10% accuracy claim. The fastest infusion had an average flow rate of 4.24 ml/hr and the slowest infusion had an average flow rate of 3.99 ml/hr.

100 ml x 10.0 ml/hr: A ten (10) piece sample produced an average flow rate of 10.30 ml/hr. The resulting average is within its ±10% accuracy claim. The fastest infusion had an average flow rate of 10.80 ml/hr and the slowest infusion had an average flow rate of 9.65 ml/hr.

Back Pressure (Head Height) Comparison: Approximately 0.57 psi pressure difference results per 16" head height. Thus, a 10% flow rate change may occur for each 16" head height difference from nominal assuming a 6 psi pressure source.

3.3 **Drug Delivery Comparison**: Local anesthetics have densities similar to normal saline (e.g. 1.002 to 1.005 for Ropivacaine HCl vs. 1.0045 for normal saline) and should not affect flow rate. Product labeling includes a statement as to delivery times and the possible deviation from nominal due to drug viscosity.

3.4 **Safety / Alarm Functions**

3.4.1 The Paragon pump and administration set provide a continuous fixed flow and as such is not subject to fluid runaway conditions similar to that of some electronic pumps.

3.4.2 The Paragon pump will not be recommended for any application that exceeds the minimum internal pressure of the system.

3.4.3 If for any reason the patient needs to stop his or her infusions, each administration set is supplied with a pinch clamp to stop the infusion.

3.4.4 This device contains no alarms or indicators for flow other than visual.

3.4.5 This device contains no alarms or indicators to detect air in line or an occlusion; however, each set may include an integrated air-eliminating filter.

4.0 BIOLOGICAL SPECIFICATIONS

4.1 Biological testing is in conformance with ISO 10993 Part 1 for all fluid path components of the Paragon administration set.

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

5.1.1 There are no specific drugs referenced in the labeling for the Paragon Infusion Kit.

5.1.2 The Paragon Infusion Kit is intended for use with general local anesthetics and epidural medications.

5.2 Drug Stability

5.2.1 There are no drugs included in the Paragon Infusion Kit.

6.0 INTENDED USE

6.1 The Paragon Infusion Kit is intended to provide continuous infusion a local anesthetic directly into an intraoperative (soft tissue / body cavity) site for general surgery for postoperative pain management.

6.2 Additional routes of administration include percutaneous, subcutaneous, intramuscular and epidural infusion.

6.3 The Paragon pump is re-usable. The disposable Paragon administration set is single patient use only.

6.4 No testing has been conducted to determine the efficacy of the Paragon for the delivery of blood, blood products, lipids or fat emulsions. The Paragon is not intended for the delivery of blood, blood products, lipids or fat emulsions.

6.5 The Paragon is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

7.0 PACKAGING

7.1 The Paragon Kit consists of an inner pouch or tray with Tyvek lid stock surrounded by a header bag with an ETO Tyvek strip.

7.2 The Paragon administration set may be packaged in either a Tyvek pouch or Form/Fill/Seal.

7.3 The Paragon Kit components are placed in the inner tray or pouch.

7.4 Packaging is suitable for either radiation or ETO sterilization.

8.0 STERILIZATION INFORMATION

Note: The kit components of the Paragon Infusion Kit may be purchased non-sterile and packaged by I-Flow or sterile from the manufacture. The Paragon administration set and non-sterile purchased components shall be sterilized as follows:

8.1 The methods of sterilization are gamma radiation (Cobalt 60) or ETO gas.

9.0 COMPARISON TO LEGALLY MARKETED DEVICES

See Table 1 that follows this section for more specific information.

9.1 Intended Use

9.1.1 The Paragon Infusion Kit, the PainBuster Infusion Kit and the Sgarlato Pain Control Infusion Pump (PCIP) have the same intended use:

9.1.1.1 To provide continuous infusion of a local anesthetic directly into the intraoperative site for general surgery for postoperative pain management.

9.1.2 The predicate Paragon Infusion System and Homepump C-Series are intended for general infusion use, including chemotherapy and pain management.

9.2 Device Descriptions

9.2.1 The Paragon Infusion Kit

9.2.1.1 The Paragon Infusion Kit is identical to the predicate PainBuster Infusion Kit with the exception of the Paragon pump and administration set replacing the PainBuster pump.

9.2.1.2 The Paragon Infusion Kit uses the same mechanical, reusable Paragon pump as the predicate Paragon Infusion System.

9.2.1.3 The Paragon Infusion Kit uses the same Paragon Administration Set as the Paragon Infusion System.

9.2.2 The Paragon Infusion System

9.2.2.1 The Paragon Infusion Kit uses the same pump and administration sets as the Paragon Infusion System (K923875).

9.2.3 The Sgarlato Pain Control Infusion Pump (PCIP)

9.2.3.1 The Sgarlato PCIP consists of a kit very similar to the Paragon and PainBuster Infusion Kit. These kits consist of an infusion pump and administration set, catheter, needle, syringe, Y adapter, carry case, dressing, tape and gauze.

9.2.3.2 The Sgarlato kit uses a disposable, spring driven syringe pump with integrated administration set.

9.2.4 The Homepump C-Series

9.2.4.1 The Homepump C-Series consists of a disposable, elastomeric infusion pump with integrated administration set.

9.2.5 Specifications

9.2.5.1 The Paragon Infusion Kit, PainBuster Infusion Kit and Sgarlato PCIP have similar fill volumes and flow rates, see Table 1.

9.2.6 Flow Control

9.2.6.1 The Paragon Infusion Kit and all its predicate devices use either a glass orifice or PVC tubing to control the flow rate.

9.2.7 Materials

9.2.7.1 The Paragon Infusion Kit uses the same Paragon Administration Set as the Paragon Infusion System. All fluid path materials of the Paragon Administration Set are in conformance with ISO 10993 Part 1.

9.2.8 Based upon the data presented in this section 9.0 and Table 1, I-Flow Corporation has determined that the Paragon Infusion Kit is substantially equivalent to the named predicate devices.

Table 1
Comparison to Legally Marketed Devices

Comparison Element	Paragon Infusion Kit (subject device)	SE[1] Paragon Infusion System (K923875)	SE[1] PainBuster Infusion Kit (K980558, K982946)	SE[1] Sgarlato PCIP (K896422)	SE[1] Homepump C-Series (K944692)
Intended Use	To provide continuous infusion of a local anesthetic directly into the intraoperative site for general surgery for postoperative pain management.	General infusion use, including chemotherapy and pain management.	To provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.	To provide continuous infusion of a local anesthetic directly into the surgical wound site for postoperative pain management.	General infusion use, including chemotherapy and pain management.
Routes of Administration	Percutaneous, subcutaneous, intramuscular and epidural	Intravenous	Percutaneous and subcutaneous	Percutaneous, subcutaneous and epidural	Intravenous, intra-arterial, epidural or subcutaneous
Contraindications	Not intended for intravenous or intra-arterial delivery. Not intended for delivery of blood, blood products, lipids or fat emulsions.	Not intended for delivery of blood, blood products, lipids or fat emulsions.	Not intended for intravenous, intra-arterial or epidural delivery. Not intended for delivery of blood, blood products, lipids or fat emulsions.	Not intended for rapid infusions. Not intended for intravenous infusion.	Not intended for delivery of blood, blood products, lipids or fat emulsions.
Reuse Capability	Re-usable pump, single patient use disposable administration set	Re-usable pump, single patient use disposable administration set	Disposable, single patient use	Disposable, single patient use	Disposable, single patient use
Description	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.	Sold empty and capable of being filled via a fill port.
Fill Volumes	100 ml	100 ml	50 to 270 ml	50 to 100 ml	50 to 500 ml
Flow Rates	0.5, 1.0, 2.0, 4.0 or 10.0 ml/hr	0.5 to 200 ml/hr	0.5, 1.0, 2.0, 5.0 or 10.0 ml/hr	0.5, 1.0 or 2.0 ml/hr	0.5 to 500 ml/hr
Pump Type	Mechanical spring	Mechanical spring	Elastomeric Pump	Spring driven syringe pump	Elastomeric Pump
Power Requirements	None	None	None	None	None
Pump Mechanism	Constant pressure is applied to the fluid reservoir.	Constant pressure is applied to the fluid reservoir.	Constant pressure is applied to the fluid reservoir.	Constant pressure is applied to the fluid reservoir.	Constant pressure is applied to the fluid reservoir.
Pressure Source	Mechanical spring energy	Mechanical spring energy	Strain energy of elastomeric membranes	Mechanical spring energy	Strain energy of elastomeric membranes
Fluid Reservoir	PVC drug bag	PVC drug bag	Thermoplastic (Krayton) elastomeric membrane	Polypropylene plastic syringe	Thermoplastic (Krayton) elastomeric membrane
Administration Set					
Flow Control	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.	Consistent flow rate throughout the entire course of therapy is achieved by the combination of constant pressure and flow control tubing.
Safety / Alarm Functions	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.	Fixed flow rate tubing prevents fluid runaway conditions. Each administration set is supplied with a clamp to stop the infusion if necessary.

[1]SE = Substantially Equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Robert J. Bard, Esq., R.A.C.
Vice President Regulatory and Legal Affairs
I-Flow Corporation
20202 Window Drive
Lake Forest, California 92630

Re: K984063
Trade Name: Paragon Basal/Bolus Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 11, 1998
Received: November 16, 1998

Dear Mr. Bard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984063

Device Name: Paragon Basal/Bolus Administration Set

Indications for Use:

1. The Paragon Basal/Bolus Administration Set is intended to provide a continuous, basal level infusion of medication and to allow patient controlled bolus delivery. The bolus component of the administration set enables fixed boluses of medication to be delivered upon demand by the patient or healthcare provider. The Paragon Basal/Bolus Administration Set routes of administration include: intravenous, epidural, intramuscular and subcutaneous.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984063